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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/533,522

05/02/2005

Istvan Hudak

9007-1011

1625

466

7590

01/12/2007

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/533,522	Applicant(s) HUDAK, ISTVAN	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/13/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The preliminary amendment to the claims filed 05/02/2005 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The claims are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. One example of a grammatical error is found in claim 9 line 4 the phrase "having viscosity is lower than". For time purposes the examiner will not cite all instances of grammatical and idiomatic errors but will allow the applicants and the agents for applicants to review and amend all instances of grammatical and idiomatic errors on their own time.

Claims 2-3,12-14 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically the phrase "usual auxiliary" is indefinite as to what types of auxiliaries are encompassed within the limitation of "usual". It is suggested by the examiner that specific examples or a Markush group of auxiliaries is brought into the claims.

Regarding claims 4-11,15-22,24-31, the words "preferred and preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is suggested by the examiner to delete the words "preferred and preferably" and whatever further limitation

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comes after those words, such as "preferably 1,4-buthanediol" are deleted. For examination purposes the examiner simply ignored the preferred embodiments in the claims.

Claims 5,16 and 25 recites the limitation "main diol component" in lines 2. There is insufficient antecedent basis for this limitation in the claim. The examiner realizes that polyurethane can be comprised of a diol but polyurethanes can comprise numerous types of polyols besides diols, therefore it is not obvious or inherent from the recitation of polyurethane that it would constitute a diol component only a polyol component. It is suggested by the examiner to amend the claims 5,16 and 245 to recite the following "where the polyurethane is comprised of a main diol component" instead of "where the main diol component". To expedite the examining process the examiner still searched for a diol component as specified in applicants specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,8-9,11-15,19-20,22-24,28-29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Garibaldi (US 6,296,604 B1, cited by applicants).

Garibaldi teaches a biocompatible composition comprised of a precipitating polymer such as polyurethane, an adhesive and a magnetic embolic agent (including barium or tantalum), the polyurethane was dissolved in a biocompatible solvent such as

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DMSO and EtOH. See col 2 lin 63-col 3 lin 7, lin 53-62, col 4 lin 13-23 and claims 1-9 and 14. Regarding the limitation that the composition is used to fill or short-circuit a vascular cavity, Garibaldi teaches several uses for the composition to treat vascular defects including covering aneurisms and covering injured sections on the inside of a vessel, thus meeting the limitation of filling a vascular cavity. See col 8 lin 10-54.

Regarding the limitations on the viscosity of the composition Garibaldi claims a viscosity between about 30 and about 1500 centipoise within applicants specified range, the examiner assumes the viscosity measurements would be conducted at room temperature.

Claims 1-3,5-10,12-14,16-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Marinovic (EP 0 280,451, cited by applicants).

Marinovic teaches polyurethanes prepared by mixing prepolymers of diisocyanate (including MDI) and polyols such as polypropylene glycol, the polyurethanes were useful as space filling adhesive sealants in surgery. See abstract, page 3 lin 14-58, page 4 lin 6-58 and page 6 lin 11-36. The polyurethanes within Marinovic could be used in a package containing separate compartments for the polymer and an aqueous solution containing a chain extender (meets limitation of usual auxiliary and solvent), the polymer and aqueous solution are conveniently mixed prior to use as space filling tissue adhesives. See claims 12-16. Regarding the limitations regarding MW of the polyurethane, Marinovic teaches that the polyglycol has an average MW of 650-5000 and the diisocyanate/polyglycol monomers are in a 2:1 ratio, therefore the MW of the entire polymer would be between 1,950-15,000, within

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applicants specified range. Regarding the limitation that the diol component is HO-R'-OH, where R' stands for a C1-C8 alkylene group, polypropylene glycol is formed by a condensation of the C3 diol propylene glycol, as evidenced by applicants own specification polypropylene glycol is a special sub-group of diols and therefore meets applicants limitation above. See [0072] in US 2006/0008499 A1 patent application publication of 10/533,522.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garibaldi (US 6,296,604 B1, cited by applicants) in view of Marinovic (EP 0 280,451, cited by applicants).

Garibaldi is disclosed above. While Garibaldi discloses the use of polyurethanes the patent does not detail the exact diisocyanate and polyol monomers that were used to produce the polymer and the patent is silent on the MW of the polyurethanes.

Marinovic is disclosed above.

Marinovic is used to primarily show that polyurethanes within applicants claimed MW range and formed by the condensation products of the specific diisocyanates and polyols as currently claimed by applicant was already known to be used as an adhesive sealant in surgery. The advantages of the disclosed adhesives within Marinovic is its

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application as a viscous liquid which can be sculpted, once in place the adhesive is rubbery and not brittle or subject to shattering and the adhesive is non-toxic.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Garibaldi discloses all of applicants claimed invention but is silent on the monomers used to produce the polymer and the polymers molecular weight while Marinovic discloses that polyurethanes within applicants claimed MW range and formed by the condensation products of the specific diisocyanates and polyols as claimed was already known to be used as an adhesive sealant in surgery. The motivation to combine the above documents would be to produce a composition comprised of a polyurethane an auxiliary and solvent useful for filling vascular cavities. The advantage of the disclosed composition with a polyurethane within a specific MW and produced by the condensation of specific monomers such as MDI and C1-C8 diols would be that the polyurethane would have a desirable viscosity which is rubbery when applied and not brittle and is non-toxic all of which are obviously desirable traits in surgical adhesives. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

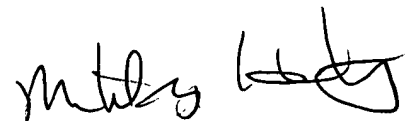
Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'm. hartley', with a stylized flourish at the end.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER